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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,362	10/15/2004	Perry J Blackshear	4239-64828-02	3754

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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,362	BLACKSHEAR ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37.CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31, 33-41, 43-46, 49-59 and 61-64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31, 33-41, 43-46, 49-59 and 61-64 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-31, 33-41, 43-46, 49-59 and 61-64 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claims 1-4, 14, 22-24, and 58, drawn to a substantially purified RFX4_v3 polypeptide and a method for screening compounds for the ability to alter RFX4_v3 activity using the same.

Group II, claims 5-13, 15-21, 25-27, drawn to an isolated nucleic acid molecule encoding a RFX4_v3 polypeptide, a vector, a host cell comprising the same and a method for producing a variant of the same.

Group III, claims 28-30, drawn to a method for detecting a nucleic acid molecule in a biological sample.

Group IV, claims 31, 33-35, 40-41 and 44-45, drawn to a method for identifying a subject at risk of developing RFX4_v3 linked hydrocephalus by detecting in the subject a mutation in a RFX4 v3 nucleotide sequence, and a kit comprising a nucleic acid probe that specifically detects a mutation in a RFX4_v3 allele.

Group V, claims 31, 36-41 and 43, drawn to a method for identifying a subject at risk of developing RFX4_v3 linked hydrocephalus by detecting in the subject a mutation in a RFX4 v3 polypeptide.

Group VI, claims 44 and 46, drawn to a kit comprising an antibody that specifically binds and detects a mutation in the protein expressed by a mutated RFX4 v3 allele.

Group VII, claim 49, drawn to an antibody that specifically binds to a substantially purified RFX4 v3 polypeptide.

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Group VIII, claims 50-57, drawn to a method for generating a non-human transgenic animal with a knockout for the RFX4_v3 gene, and a transgenic mouse whose somatic and germ cells comprise a disrupted endogenous RFX4_v3 gene.

Group IX, claims 59, 61-62, drawn to a pharmaceutical composition comprising a therapeutically effective amount of RFX4_v3 polypeptide, variant or portion thereof and a pharmaceutically acceptable carrier, and a method of treating congenital hydrocephalus in a subject using the same.

Group X, claims 59, 61 and 63-64, drawn to a pharmaceutical composition comprising a therapeutically effective amount of a nucleic acid sequence encoding a RFX4_v3 polypeptide, variant or portion thereof and a pharmaceutically acceptable carrier, and a method of treating congenital hydrocephalus in a subject using the same.

The currently claimed subject matter, Inventions of Groups I-X, lacks unity of invention according to Rule 13.1 PCT for the following reasons.

The substantially purified RFX4_v3 polypeptide of Group I, the isolated nucleic acid molecule of Group II, the antibody that specifically binds and detects a mutation in a RFX4_v3 polypeptide of Group VI, an antibody that binds to a RFX4_v3 polypeptide of Group VII, a transgenic mouse of Group VIII, a pharmaceutical composition comprising a therapeutically effective amount of a RFX4_v3 polypeptide of Group IX, and a pharmaceutical composition comprising a therapeutically effective amount of a nucleic acid sequence encoding a RFX4_v3 polypeptide of Group X are compositions that are different chemically one from the others, as well as each composition has different properties and/or characteristics one from the others. For examples, the polypeptide of Group I is made up of amino acid residues and different in the primary sequence from the antibody of Group VI or the antibody of Group VII. The isolated nucleic acid molecule of Group II is made up of nucleotides. Unlike the antibody of

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Group VII, the antibody of Group VI specifically binds and detects a mutation in a RFX4_v3 polypeptide. The transgenic mouse of Group VIII is a living entity, physically and chemically different from the other compositions. The pharmaceutical compositions of Groups IX and X are different chemically one from the other, as well as they have different components (e.g., a pharmaceutically acceptable carrier) and unlike other compositions they have pharmaceutical properties.

The methods in Groups I-V, VIII-X are different one from the others by having different starting materials, different method steps and different desired end-results. For examples, the first method of use in Group I is directed to a screening method for one or more test compounds; the first method of use in Group II is drawn to a method for producing a variant polypeptide of the present invention involving the step of mutagenizing a wild type nucleic acid sequence; the method in Group III is for detecting a nucleic acid molecule in a biological sample; the method of Group IV is for detecting in the subject a mutation in a RFX4_v3 nucleotide sequence; the method of Group V is for detecting in the subject a mutation in a RFX4_v3 polypeptide; the method of Group VIII is for generating a non-human transgenic animal with a knockout for the a RFX4_v3 gene; the methods in Groups IX and X are methods for treating congenital hydrocephalus using a therapeutically effective amount of RFX4_v3 polypeptide and a nucleic acid encoding the same, respectively. Each different method step can be considered to be a "special technical feature"; and therefore the methods listed in Groups I-V, VIII-X lack the same or corresponding special technical features.

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Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Weitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.


QUANG NGUYEN, PH.D.
PATENT EXAMINER